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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	17

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,709	BARON ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,23,24 and 31-44* is/are pending in the application.

4a) Of the above claim(s) *1-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24 and 31-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application filed August 28, 2001 claims benefit to provisional application 60/228,450, filed August 29, 2000.

Claims 1-18, 23, 24 and 31-44 are pending.

Election/Restriction

Applicant's election with traverse of Group IV, claims 23, 24 and 31-44, and *in vivo* methods in transgenic animals in Paper No. 16 is acknowledged. The traversal is on the ground(s) that Examiner has not properly set forth the requirements for the election of "patentably distinct" species between *in vivo* and *in vitro* methods. Applicants note that the instantly claimed invention is based on the observation that over-expression of ΔFosB in transgenic mice results in increased bone formation and inhibition of adipocyte formation. See Applicants' response filed July 15, 2003, bridging pages 1-2. This is found persuasive because while *in vitro* and *in vivo* methodology usually requires unique method steps for delivery and detecting affects of said delivery, the instantly claimed methods are simple and straightforward. Because the method requires inducing ΔFosB and looking at the affect on gene expression in a cell, the affect would be inherent to a cell either *in vitro* and *in vivo*. Because the observed affect on the cell will be the same either *in vitro* and *in vivo,* they would not present patentably distinct methods or results. Therefore, for the reasons above the election of species is withdrawn.

With respect to the restriction as it applies to the inventions set forth in Groups I-IV, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

Claims 1-18, 23, 24 and 31-44 are pending. Claims 1-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 16. Claims 23, 24, 31-44, drawn to a method of identifying genes which are modulated by ΔFosB are currently under examination.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Specifically, on pages 53-56 a list of references is provided, however not all the references are listed in the IDS (see paper number 10) nor are copies of the references provided. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claim 38 is objected to because of the following informalities: Claim 38 ends with a semicolon. It is unclear if this is a typographical error or if the claim is incomplete. For the sake of compact prosecution it will be interpreted as a typographical error and the claim will be interpreted to be complete.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention consists of using several specific cell lines as recited in the claim. Since the cell lines are essential to practicing the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the cell lines are not so obtainable or available, the requirements of 35 U.S.C. 112, regarding "how to make", may be satisfied by a deposit of cell lines. It is noted that the specification provides literal support for these specific cell lines and that they exist, however there is no

indication in the specification as to public availability (specification pages 18 and 47-working example). If a deposit has been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific cell lines have been deposited under the Budapest Treaty and that the cell lines will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement.

It the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request of for the effective life of the patent, whichever is longer; and,

(d) a test of viability of the biological material at the time of deposit (see 37 CFR 1.807); and,

(e) the deposit will be replaced if it should ever become inviable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, 35, 38, 40 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34 and 35 are vague and confusing. Both claims are drawn to the method of claim 31 which uses a cell *in vitro*, and while a cell lysate and nuclear extract are less than a complete cell, they do not further limit the claim because they are drawn to a use of different product. The claims require observing changes in gene expression (see claim 23) which can not be done using cell lysate or nuclear extracts. More clearly setting forth the relationship of the cell lysate and nuclear extract and how they are used in the *in vitro* method may obviate the basis of the rejection.

Claim 38 is confusing and redundant in the recitation of "the cell is in an animal" because it depends on claim 37 which is drawn to a cell *in vivo*. If the cell is *in vivo*, it is unclear how it can be in any other context but in an animal.

Claim 40 is vague and incomplete. The claim indicates that the method of claim 23 is performed in a "high throughput format", however it is not clear what the format is that makes it high throughput because there are no method steps indicating how to practice the method of claim 40. Additionally, it is not clear if this high throughput method is directed to step (a) or step (b), and as set forth above how either would be performed.

Claim 42 is confusing because step (b) of claim 23 requires determining gene which are differentially expressed and it is unclear how claim 42, a method requiring isolation of RNA further limits this step. More clearly setting forth specific method steps and the relationship of the method steps may obviate the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 24, 31, 32, 36-39, 41-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Nestler *et al.* (IDS reference).

Initially, it is noted that Nestler *et al.* was published on the world wide web November 27, 1998, qualifying it as a 102(b) type reference (see page 10, bottom of first column). Nestler *et al.* teaches the role of ΔFosB in neural plasticity *in vitro* and *in vivo* in animal models (page 12, bridging first and second columns). Nestler *et al.* teach that ΔFosB is known to be induced by cocaine, amphetamine nicotine, opiates, antidepressants, and antipsychotic (see Table 1). Because Nestler *et al.* practices the methods in animals all the cells of the animal are affected including those set forth in claim 32. Further, Nestler *et al.* teach to generate transgenic ΔFosB

mice and use said mice in analyzing the affect of ΔFosB (pages 1-15, section 4 and 5). Nestler *et al.* isolate RNA and do Northern blot analysis to determine the affects of ΔFosB expression in a transgenic animal in various parts of the brains and in various organs and tissues (figure 4). Nestler *et al.* teach that they have used DNA array technology with early success (page 16, end of section 5, citing results of citation 7-Chen *et al.* IDS reference). Nestler *et al.* teach that ΔFosB is a transcription factor whose expression is an early response to stimuli (page 10, abstract and introduction section) and that the materials and methods disclosed are used to detect altered expression of specific target genes (page 16, end of section 6). The use of a DNA array is being considered high throughput because it is the only methodology specifically recited in the claims and the specification in which multiple samples are assayed (claim 40). However, it is noted that in general simply setting forth that a known method is done by using automated methods is not considered patentable. See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958) where it was held that a process that was previously done manually and the only difference with the prior art and the claimed invention is that the process is automated and accomplishes the same result is not sufficient to distinguish it over the prior art. See MPEP 2144.iii.

Claims 23, 31, 32 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Agamemnon *et al.* (J Cell Biol 122:685-701, 1993).

Agamemnon *et al.* teach a transgenic mouse model where a c-fos transgene is under the control LTR promoter and expressed in a variety of tissues. The expression of the transgene

results in the expression of the exogenous fosB transcript (see figure 2, panel B and summarized in Table I). Agamemnon *et al.* teach that the expression can be detected in the bone (table I) and results in observable phenotypic changes in the bones (see results in figure 3). Agamemnon *et al.* teach the isolation of cell lines (starting on bottom of page 691 and Table III), and the characterization of the affect of the transgene on specific gene expression *in vivo* and *in vitro* in the isolated cell lines (see Figures 5 and 8 for example).

Conclusion

No claim is allowed. Claims 33, 34, and 35 are free of the art of record, however they are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

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1632